The Physiological Impact of Wearing an N95 Mask during Hemodialysis as a Precaution against SARS in Patients with End-Stage Renal Disease

Tze-Wah Kao,[1] Kuo-Chiang Huang,[1] Yu-Ling Huang,[2] Tun-Jun Tsai,[1] Bor-Shen Hsieh,[1] and Ming-Shiou Wu[1]

Background and Purpose: Most patients with end-stage renal disease (ERSD) visiting our hospital for hemodialysis treatment during the SARS outbreak wore an N95 mask. Data on the physiological stress imposed by the wearing of N95 masks remains limited. This study investigated the physiological impact of wearing an N95 mask during hemodialysis (HD) on patients with ESRD.
Methods: ESRD patients who received regular HD at National Taiwan University Hospital between April to June 2003 were enrolled. Each patient wore a new N95 mask (3M Model 8210) during HD (4 hours). Vital signs, clinical symptoms and arterial blood gas measured before and at the end of HD were compared.
Results: Thirty nine patients (23 men; mean age, 57.2 years) were recruited for participation in the study. Seventy percent of the patients showed a reduction in partial pressure of oxygen (PaO_2), and 19% developed various degrees of hypoxemia. Wearing an N95 mask significantly reduced the PaO_2 level (101.7 ± 12.6 to 92.7 ± 15.8 mm Hg, $p = 0.006$), increased the respiratory rate (16.8 ± 2.8 to 18.8 ± 2.7/min, $p < 0.001$), and increased the occurrence of chest discomfort (3 to 11 patients, $p = 0.014$) and respiratory distress (1 to 17 patients, $p < 0.001$). Baseline PaO_2 level was the only significant predictor of the magnitude of PaO_2 reduction ($p < 0.001$).
Conclusion: Wearing an N95 mask for 4 hours during HD significantly reduced PaO_2 and increased respiratory adverse effects in ESRD patients.

Key words: Blood gas analysis; Hemodialysis; Hypoxemia; Masks; Oxygen

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The outbreak of severe acute respiratory syndrome (SARS) worldwide was characterized by efficient nosocomial transmission of the virus.[1] The majority of SARS cases were associated with transmission in health care settings[2] or related to hospital exposure.[3] The use of masks, either surgical or N95 type, was shown to be effective in preventing transmission of SARS from patients to healthy hospital staff.[4] During the epidemic and nosocomial spread of SARS from April to June 2003 in Taiwan, more than 100 SARS patients were hospitalized and treated at National Taiwan University Hospital (NTUH).

During the outbreak, all medical staff were required to wear N95 masks when having close contact with patients. Most end-stage renal disease (ESRD) patients coming to our hospital thrice a week for hemodialysis (HD) treatment wore N95 masks as well due to a pervading fear of SARS. However, despite the need for this precaution, there was a lack of data on whether ESRD patients could safely tolerate the use of N95 masks during HD. There were few previous studies evaluating the physiological stress imposed by N95 masks and these focused mainly on healthy young men doing exercise.[5] Our ESRD patients, on the other hand, were generally much older. Although patients lay quietly during HD with minimal physical activity, these patients were more likely to have concomitant pulmonary and/or cardiovascular disorders which rendered them unfit to use respirators.[6] HD patients also frequently have anemia and left ventricular hypertrophy which greatly increase their cardiac workload.[7] Oxygen supplementation is sometimes needed in these patients during HD owing to angina pectoris or congestive heart failure. This study investigated the impact of wearing N95 masks during HD on ESRD patients and whether these patients could safely tolerate the use of this kind of mask as a respiratory protective device during an HD session.

[1]Department of Internal Medicine, National Taiwan University Hospital, Taipei; [2]Department of Psychiatry, Shin Kong Wu Ho-Su Memorial Hospital, Taipei, Taiwan.
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Reprint requests and correspondence: Dr. Ming-Shiou Wu, Department of Internal Medicine, National Taiwan University Hospital, No. 7, Chung-Shan South Road, Taipei, Taiwan.

Methods

Patients

ESRD patients who received regular HD at NTUH between April to June 2003 were invited to join the study. Patients were considered eligible for the study if they met the following inclusion criteria: 1) had facial contours that permitted good fitting of N95 masks; 2) used either an arteriovenous (AV) graft or fistula but not a venous catheter for vascular access; 3) did not depend on oxygen supply during previous HD sessions; 4) did not breathe through a tracheostomy; and 5) were willing to wear an N95 mask continuously throughout an HD session. Patients who had subjective respiratory distress or an arterial oxygen saturation (SaO_2) level below 92% measured by a pulse oximeter before the start of the study were excluded. Baseline demographic and clinical characteristics of the participants including age, gender, cause of renal failure and comorbid conditions were recorded. Comorbid condition referred to diseases other than renal failure present at the time of study. This research was approved by the institutional review board of this hospital, and informed consent was obtained from each participant before entry into the study.

Methods

At the start of the study before wearing the N95 mask, vital signs were measured, including blood pressure, pulse rate and respiratory rate. Clinical symptoms, including headache, dizziness, tiredness, facial itchiness, nasal stuffiness, decreased ability to concentrate, chest discomfort or respiratory distress were recorded if present. The severity of the symptoms was subjectively graded by the patients as 'mild', 'moderate' or 'severe'. A new disposable N95 mask (Model 8210; 3M, Occupational Health and Environmental Safety Division/3M, St. Paul, Minnesota, USA) was then put on and fixed tightly by each participant under the supervision of the physician in charge according to instructions of the manufacturer. Slight self-adjustment of the mask was allowed during the HD session. As soon as the N95 mask had been placed, 2 HD needles were inserted into the patient's AV shunt, one at the arterial end and the other at the venous end. Using a 2-mL syringe which had been rinsed with a small amount of heparin, 2 mL of blood from each patient was drawn from the arterial end of the AV shunt at the start of the dialysis. Trapped air was rapidly expelled from the syringe. The syringe needle was immediately replaced by a plastic plug which prevented gas movement between the air and the blood. The syringe with the blood drawn was then put into an ice bath.[8] Arterial blood gas (ABG) including partial pressure of oxygen (PaO_2) and partial pressure of carbon dioxide ($PaCO_2$) was analyzed by a blood gas machine (Bayer, USA) within 30 minutes after the blood had been drawn, and represented the patient's baseline blood gas levels. Hematocrit level was also obtained at the beginning of the dialysis.

All patients received bicarbonate dialysate and non-cuprophan dialyzer membranes for HD. Vital signs were monitored carefully during the whole HD session, which lasted for 4 hours. At the end of the dialysis, clinical symptoms and their severity were reassessed. Vital signs were rechecked and ultrafiltration volume was recorded. Another 2 mL of blood was drawn from the arterial end of the AV shunt with a new syringe. ABG was again analyzed using the same method and machine within 30 minutes, and represented the blood gas levels after prolonged use of an N95 mask. All parameters including vital signs, clinical symptoms and ABG were measured twice for each patient: once before the use of the N95 mask and once after.

Statistical analysis

The primary outcome measure was the change in PaO_2 level before and after the use of the N95 mask. Secondary outcome measures included changes in $PaCO_2$, vital signs, and clinical symptoms. Mild hypoxemia was defined as a PaO_2 level less than 80 mm Hg and equal to or greater than 70 mm Hg, while PaO_2 levels of less than 70 and 60 mm Hg represented moderate and severe hypoxemia, respectively. Data in the following categories were considered as outlying and excluded from the analysis: 1) a PaO_2 level equal to or greater than 130 mm Hg and 2) a $PaCO_2$ level greater than 70 mm Hg after the use of an N95 mask. Paired *t* tests were conducted to compare the baseline and the post-HD vital signs as well as blood gas levels. Changes in clinical symptoms were analyzed using Wilcoxon signed rank test. Univariate linear regression was used to investigate the effect of various potential risk factors on the amount of change in PaO_2 level. For the clinical variables in which significant differences between the baseline and the post-HD were demonstrated, univariate as well as multivariate regressions were performed to identify their predictors. The risk factors examined included age, gender, diabetes mellitus (DM), cardiovascular disease, baseline vital signs (pulse rate, respiratory rate, systolic blood pressure, diastolic blood pressure), hematocrit level, and ultrafiltration volume. A *p* value of less than 0.05 was considered statistically significant; all tests were 2-tailed. The statistical analyses were performed with the statistical package SAS for Windows (Version 8.0).

Results

Fifty patients received HD regularly at our hospital during the study period. Nine of these patients were considered ineligible for the study for the following reasons: 2 could not wear an N95 mask tightly due to small faces; 3 were dialyzed via double-lumen catheters; 3 depended on oxygen supply during previous HD; and 1 breathed through a tracheostomy. Another 2 patients who had respiratory distress before the start of the study were excluded. A total of 39 eligible patients (23 men, 16 women) were included in the study after informed consent was obtained. Their mean age was 57.2 years (range, 25 to 88 years). Ten of them (25.6%) had DM and 14 (35.9%) had cardiovascular disease. The mean ultrafiltration volume was 2.43 L, and the mean hematocrit level was 32.9%.

About 70% of the subjects had a reduction in PaO_2 at the end of the 4-hour study period. Seven (19%) patients were found to have various degrees of hypoxemia — mild in 4 patients, moderate in 2, and severe in 1. The mean PaO_2 level dropped significantly from 101.7 ± 12.6 (mean ± SD) mm Hg at baseline to 92.7 ± 15.8 mm Hg at post-HD with a net decrease of 9.0 ± 18.5 mm Hg ($p = 0.006$) [Fig.]. This reduction was not correlated with age, gender, the presence of DM or cardiovascular disease, ultrafiltration volume or hematocrit level. The baseline PaO_2 level was the only significant predictor of the magnitude of PaO_2 reduction (linear regression: standardized B = -0.524, t = -3.74, $p < 0.001$). However, among the 7 patients who developed hypoxemia, 6 were over 60 years old, and 3 had underlying cardiovascular disease. There was no significant change in $PaCO_2$ levels (baseline: 39.7 ± 4.3 mm Hg; post-HD; 40.7 ± 3.2 mm Hg; change: 1.0 ± 4.1 mm Hg; $p = 0.136$) after wearing an N95 mask for 4 hours.

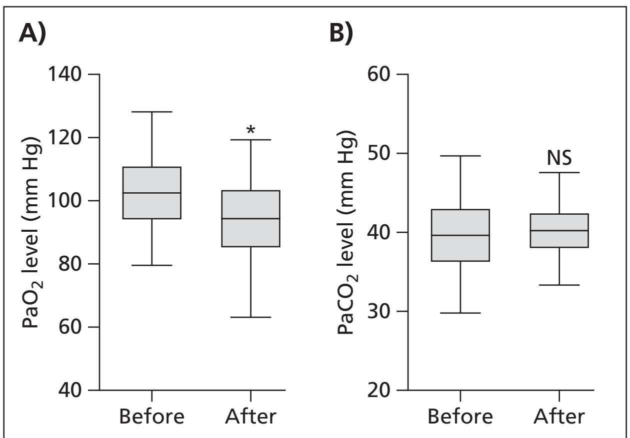

Fig. Changes in partial pressure of oxygen (PaO_2; A) and partial pressure of carbon dioxide ($PaCO_2$; B) levels before and after prolonged use of N95 masks during hemodialysis in end-stage renal disease patients. NS = not significant. * $p < 0.05$.

Table 2. Symptoms before and after the use of N95 masks in 39 patients with end-stage renal disease undergoing hemodialysis.

Symptom	Before mask use (no. of patients)	After mask use (no. of patients)	*p* value
Headache	2	2	1.000
Dizziness	2	6	0.289
Tiredness	7	6	1.000
Chest discomfort	3	11	0.014
Respiratory distress	1	17	< 0.001
Decreased ability to concentrate	2	4	0.688
Ear pain	0	5	0.063
Facial itchiness	2	3	1.000
Nasal symptoms	3	2	1.000
Others	0	2	0.500

Changes in vital signs before and after prolonged use of an N95 mask are shown in Table 1. Respiratory rate increased significantly after wearing an N95 mask for 4 hours ($p < 0.001$). There was no significant change in pulse rate or blood pressure.

Symptoms experienced by patients wearing N95 masks are shown in Table 2. Wearing an N95 mask during HD significantly increased the incidence of chest discomfort ($p = 0.014$) and respiratory distress ($p < 0.001$). No significant risk factor for these clinical symptoms could be identified.

Discussion

This study is the first to evaluate the physiological impact of wearing N95 masks during HD on patients with ESRD. Our investigation demonstrated that wearing N95 masks for 4 hours during HD resulted in a PaO_2 reduction in the majority (70%) of patients and caused various degrees of hypoxemia in nearly

Table 1. Vital signs before and after the use of N95 masks in 39 patients with end-stage renal disease undergoing hemodialysis.

Variable	Before mask use (mean ± SD)	After mask use (mean ± SD)	*p* value
Pulse rate (/min)	81.6 ± 10.0	78.3 ± 10.4	0.078
Respiratory rate (/min)	16.8 ± 2.8	18.8 ± 2.7	< 0.001
Systolic pressure (mm Hg)	136.3 ± 30.8	142.3 ± 32.9	0.165
Diastolic pressure (mm Hg)	75.4 ± 15.4	79.1 ± 16.1	0.113

SD = standard deviation.

one-fifth of all ESRD patients. It also increased the occurrence or severity of respiratory adverse effects as indicated by an increase in the respiratory rate, and the frequency of chest discomfort and respiratory distress.

The use of a control group was not feasible in this study because all patients treated with HD at NTUH during the SARS epidemic wore N95 masks. One may argue that factors other than wearing N95 masks could have caused similar changes in PaO_2 levels and respiratory symptoms/signs. However, this was less likely due to several reasons. Firstly, all of our patients used bicarbonate type dialysate and biocompatible membranes in the HD treatment. We avoided using acetate dialysate and bioincompatible membranes which had been previously reported to be associated with the development of intradialytic hypoxemia.[9–12] Moreover, if HD-related hypoxemia does occur, it is commonly observed during the first 2 hours of HD only.[13,14] Therefore, the reduction in PaO_2 levels in our study was unlikely to have been due to these 2 factors. In addition, our patients lay on a bed throughout the dialysis session, thereby minimizing the possibile confounding effects of physical activities or environmental factors. On the other hand, 'statistical regression towards the mean' could not explain the finding that all indicators of respiratory adverse effects underwent significant changes in a consistent pattern while all other non-respiratory parameters were unaffected. Due to the same reason, psychological effects such as anxiety could not explain the study results because other indicators of psychological distress such as pulse rate did not show a significant change. All evidence from this study indicated that there had been a genuine increase in respiratory adverse effects (i.e., PaO_2 reduction, increased respiratory rate, and increased frequency of chest discomfort and respiratory distress) and that wearing an N95 mask was the responsible cause.

There have been few previous studies evaluating the physiological stress imposed by the wearing of N95 masks and these focused mainly on healthy young men doing exercise.[5] In a study by Jones, both respiratory rates at rest and during exercise increased significantly under the use of N95 masks. An addition of dead air space was thought to be the main cause. Heart rate also increased as work intensity increased, but was significant only at heavy levels of work and during the recovery stage. Systolic blood pressure showed a biphasic change due to the use of N95 masks, being significantly lower at rest and higher at high levels of work. Air temperatures immediately anterior to the face were, on average, 7.5°C higher.[5] Similar to Jones' study, respiratory rates of our HD patients also significantly increased after wearing the N95 mask for 4 hours. However, the heart rates of our patients did not change significantly, probably because they were lying on a bed during HD with minimal physical activity. The small number of cases might also have contributed to this insignificant result ($p = 0.078$). Also, blood pressure of our patients did not change significantly after wearing an N95 mask for 4 hours. Previous study found that blood pressure usually decreased gradually during HD due to a continuous ultrafiltration of excess body fluid.[15] This suggests that wearing a mask may have significantly increased blood pressure even though control values could not be assessed.

Workers who wear respirators may complain of symptoms such as headache, facial pain,[16] thermal discomfort,[17] anxiety,[18] local skin reaction,[16] and decreased visual field.[19] In comparison, the most common symptoms experienced by our patients after wearing N95 masks for 4 hours were respiratory distress and chest discomfort, followed by ear pain and dizziness. Among the 7 patients who developed hypoxemia, 3 developed both respiratory distress and chest discomfort, while 2 developed respiratory distress and dizziness. The appearance of various symptoms in these patients showed compatibility with the occurrence of hypoxemia.

Several limitations in our study should be noted. The hypoxemia results might have been underestimated as slight adjustment of the N95 masks by the patients themselves was permitted during HD, especially when facial itchiness occurred. This might have allowed a small amount of air exchange which led to a higher post-HD PaO_2 level and/or a lower $PaCO_2$ level. This implies that the adverse respiratory effect of wearing N95 masks might have been more prominent than observed. However, our results reflected the real-life situation that HD patients would sometimes adjust their masks during HD, especially after prolonged use. Another limitation in our study was that the sample size was relatively small. Inadequate statistical power might have been a reason for insignificant results in the risk factors analysis.

Compared with other respirators, N95 masks are relatively comfortable, light, and flexible and can accommodate a variety of facial contours.[20] They interfere less with speech and visual acuity, and need not be maintained or cleaned. These advantages make the N95 mask a suitable candidate as a protective device against respiratory-transmitted infections. However, the benefits gained by reducing the morbidity or mortality of a target infectious disease must be weighed against the potential for immediate and severe adverse effects on respiratory functions. Our study showed that wearing an N95 mask for 4 hours during HD in patients with ESRD caused a significant

increase in respiratory adverse effects, with nearly one-fifth of patients developing hypoxemia. Our results suggest that a significant number of patients would develop clinically significant respiratory distress if there was large-scale implementation of prolonged use of N95 masks. Patients who are elderly and/or have compromised cardiopulmonary functions are expected to be at particularly high risk for developing respiratory distress, and they should be closely monitored when using N95 masks.

In conclusion, our study showed that wearing N95 masks for 4 hours during HD in patients with ESRD caused a drop in PaO_2 level in 70% of patients. The baseline PaO_2 level was a significant predictor of the amount of PaO_2 reduction. Hypoxemia developed in nearly one-fifth of patients. Respiratory rate and the occurrence of chest discomfort and respiratory distress also significantly increased. As wearing an N95 mask in patients with ESRD during HD resulted in a significant increase in respiratory adverse effects, policy-making regarding a prolonged use of N95 masks in this patient group should take these potential negative impacts into consideration.

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